IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: VIAGRA PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 1724

Judge John W. Borg

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Deposition of MICHAEL A. WITT, M.D.
(Taken by Defendants)
Atlanta, Georgia
January 21, 2009

Reported by: Lynne C. Fulwood
Certified Court Reporter

STATE OF GEORGIA
COUNTY OF COBB
DEPOSITION OF MICHAEL A. WITT, M.D.

Pursuant to Article 8.B of the RULES AND REGULATIONS OF THE BOARD OF COURT REPORTING OF THE JUDICIAL COUNCIL OF GEORGIA, I make the following disclosure:

I am a Georgia Certified Court Reporter. I am here as a representative of Veritext Reporting Company.

Veritext Reporting Company was contacted by the offices of KAYE SCHOLER, LLP, to provide court reporting services for this deposition. Veritext Reporting Company will not be taking this deposition by O.C.G.A. 15-14-37 (a) and (b).

ON BEHALF OF THE PLAINTIFF:
CHRISTOPHER GOMEZ
Attorney at Law
The Miller Firm, LLC
Two Bala Plaza, Suite 613
Bala Cynwyd, Pennsylvania 19004
610-660-0622
Cgomez@doctoratlaw.com

ON BEHALF OF THE DEFENDANT PFIZER, INC.:
LORI B. LESKIN
Attorney at Law
Kaye Scholer, LLP
425 Park Avenue
New York, New York 10022-3598
212-836-8541
Lleskin@kayescholer.com

ALSO PRESENT:
John W. Borg, Special Master
The Videographer

- - -

Deposition of MICHAEL A. WITT, M.D., taken by the Defendant Pfizer, at 1201 West Peachtree Street, One Atlanta, Center, Suite 4200, Atlanta, Georgia 30309-3424 on the 21st day of January 2009, at 2:00 p.m., before Lynne C. Fulwood, Certified Court Reporter.

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P R O C E E D I N G S,

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(Whereupon, the video camera was turned on.)

THE VIDEOGRAPHER: Good afternoon, ladies and gentlemen. It's January 21st, 2009. It's 2:06 p.m. We're in Atlanta, Georgia. We're at the offices of Alston and Bird, 1201 West Peachtree Street. This will be the deposition of Michael A. Witt, M.D.

The case is in re: Viagra Products Liability Litigation in the United States District Court, District of Minnesota, MDL docket number 1724.

My name is Rick Richey. I'm the videographer. Our Court Reporter is Lynne Fulwood and we represent Veritext New York. Would the attorneys please introduce themselves.

MS. LESKIN: Lori Leskin, Kaye Scholer for defendant Pfizer.

MR. GOMEZ: Christopher Gomez, the Miller firm for the plaintiffs.

THE VIDEOGRAPHER: Would the Court

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Reporter please swear the witness.
MICHAEL A. WITT, M.D.,
having first been duly sworn, was deposed and examined as follows:
THE COURT: Doctor, this is -- I'm John Borg. I'm the special master in this case. If a lawyer says objection, before you answer the question, please allow me to rule on it and then I'll tell you whether or not you can do that.
And if you don't understand a question or if it's not clear to you, please indicate that to whoever's asking you the question and they'll -- they're rephrase that for you. Okay. Go ahead.
EXAMINATION
BY MS. LESKIN:
Q Thank you, Judge. Good afternoon, Doctor. How are you?
A Very well.
Q As I introduced myself a few moments ago, my name is Lori Leskin and I'm here on behalf of Pfizer. When's the last time you had

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your deposition taken?
A I believe the last deposition I had was in November of 2007.
Q Okay. And that was as an expert witness?
A Correct.
(Whereupon, Witt Exhibit No. 1 was marked for identification by the court reporter.)
Q Let's start with this. I'm going to hand you what we've marked as Witt Exhibit 1. This is a copy of your curriculum vitae that was provided to us together with your expert report. Is this in fact a current version of your CV?
A Yes.
Q And does this CV accurately reflect your education and training?
A Yes.
Q Does it accurately reflect your employment history?
A Yes.
Q Does it accurately reflect your medical appointments?
A Yes.

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Q Does it accurately reflect all of your publications?
A Yes.
Q Have you had any recent publications that do not appear on this copy of your CV?
A Yes.
Q Okay. When is the most recent publications you've had?
A Oh, no, it does. I'm sorry. It does. Yeah, the most recent one is 13 on the last page so no, it does.
Q Okay. And that was going to be my question because you'll see that there's a revision date on the bottom there that says 6/21/2000? You see that?
A I do.
Q Okay. And number 13 is published in 2006?
A That's correct.
Q Okay. Have there been any publications since this article which the first author is Kort?
A No, there's not.
Q Okay. Now if you turn to the second page of your CV under employment, it's listed

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Michael A. Witt, M.D., PC in Atlanta, Georgia since June of 1995?
A Yes.
Q Are you currently in a sole -- solo practice?
A I'm -- work as a consultant in an infertility practice and essentially there sort of -- on a consulting basis.
Q And that's the Reproductive Biology Associates?
A Biology Associates, correct.
Q For the Court Reporter's sake, it's helpful if only one of us speak at a time. I know it's very obvious where my questions are going but for her sake, just let me finish the question and I'll let you finish your answer, okay?
A Yes.
Q Okay. So that's Reproductive Biology Associates, correct?
A Yes.
Q And how long have you been affiliated request Reproductive Biology Associates?
A Since June of 1995.
Q Okay. Do you have a practice outside

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of Reproductive Biology Associates?
A I do.
Q Okay. And what is the nature of that practice?
A Again, it's a consultant for an infertility practice in Florida.
Q And what's the name of that practice?
A Fertility Care.
Q And how long have you been consulting with Fertility Care?
A Since 2007.
Q What -- how do you divide your time? Is there a percentage at each practice? How does that work?
A On average, it's about twelve days a month -- I mean twelve days a year, one day a month typically.
Q That you go down to Florida?
A Correct.
Q Okay. And where in Florida is that?
A Orlando.
Q So other than your consulting work for Reproductive Biology Associates and for Fertility Care, do you have any other practice?
A The only other consulting I do, which

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is maybe once a year, is in Tennessee in Nashville, Tennessee at I think it's called if I remember right, Reproductive Specialists in Nashville, Tennessee.
Q Now you say you do that once a year?
A On average.
Q And when did that consultancy start?
A Around 2006.
Q Any other practice -- practices that you are consulting with or have on your own?
A No.
Q So outside of Reproductive Biology Associates, Fertility -- start that again. Outside of Reproductive Biology Associates, Fertility Care or Reproductive Specialists, you don't see patients; is that fair?
A Yes.
Q Okay. Are you familiar with the Southeastern Fertility Institute?
A Yes.
Q Okay. What is that group?
A That used to be a -- I don't know the actual business term. I would say a sort of a subsidiary of RBA.
Q Okay.

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A It used to be Reproductive Biology Associates, which was primarily responsible for all the in vitro fertilization care. And then there was Southeastern Fertility Institute, which took care of every other clinical aspect of the infertile couple except for in vitro fertilization. And then for branding purposes because of confusion, they just consolidated the name to Reproductive Biology Associates probably three years ago.
Q But it's in general the same practice?
A Yes.
Q And your work for the groups remain the same?
A Yes.
Q Now would you agree that the primary focus of your practice is on male infertility?
A Yes.
Q And do you treat patients other than infertile males?
A Yes.
Q Okay. And what other type of patients do you see?
A Predominantly men with sexual

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dysfunction ranging from premature ejaculation to erectile dysfunction to ejaculatory dysfunction.
Q And what percentage of the patients you see are men with sexual dysfunction?
A Currently it's about 30 percent all the patients that I see.
Q Among the three different practices?
A Yes.
Q And are any of those patients the men with sexual dysfunction that you see in Reproductive Specialists in Nashville?
A No.
Q And are any of the men with sexual dysfunction that you see at Fertility Care in Orlando?
A A small -- a small number. There's an -- it's an increasing number but it's -- but it's pretty small.
Q Of the men with sexual dysfunction that you see, what percentage of those patients are erectile dysfunction patients?
A About 80 percent.
Q Now on the Reproductive Biology Associates web site, you're listed as

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specializing in male fertility, correct?
A Correct.
Q And you'll agree that is your specialization in terms of your practice?
A That's a majority of the practice, correct.
Q Are you familiar with an organization called faculty of one thousand?
A Yes.
Q Okay. And what is faculty of one thousand?
A That is a web-based group of physicians that have been conscripted to write summaries of what they perceive the individual faculty member as pertinent to the practice of medicine in their respective field that then get put on line and then physicians can access those so that they can sort of in one place get a pretty quick overview of what are the emerging issues in respective fields.
Q And how did you come to join the faculty of one thousand, which I understand is actually more than a thousand physicians at this point?
A Probably. They just asked me. There

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was an invitation sent by them because I believe one of the people that started it is Peter Schlegel out of New York, who is also a fertility specialist that I know, and my name came with a group of names that then got an invitation sent to and you either responded positively or negative to that invitation.
Q And you're listed there on the faculty as a specialist in male infertility, right?
A Correct.
Q And there's a separate group for male sexual dysfunction, right?
A That wouldn't surprise me but, yeah.
Q And you're not listed in that group?
A I don't think so.
Q What journals do you read on a regular basis?
A I would say there's probably four -- well, there's five actually. There's the Journal of Urology. There's the British Journal of Urology. There's Fertility and Sterility, Human Reproduction and I believe it's the Journal of Sexual Medicine.
Q And do you attend meetings of the

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American Urological Association?
A Yes.
Q Have you ever been subject to disciplinary action by any medical licensing entity?
A No.
Q Your CV lists medical licensing in five states?
A Yes.
Q Right? Georgia, Massachusetts, Tennessee, Oregon and Florida?
A Correct.
Q And given your testimony, I'm assuming that your licensure in Tennessee, Florida and Georgia remain active?
A Yes.
Q Is your licensing in Massachusetts still active?
A No.
Q And how about in Oregon?
A That's a good question. I think it still is. Yeah, I think it still is.
Q And you're licensed because that's where you completed your medical degree?
A Correct.

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Q Okay. And your licensing was in Massachusetts because that's where you did your residency?
A Correct.
Q Okay. Do you teach any courses?
A Not currently.
Q When you were at Emory, did you teach any courses?
A No didactic courses.
Q Nothing in the classroom?
A Right.
Q And you made that distinction for a reason so what kind of courses did you teach?
A Well, there was rounds and there was presentations to the residents and there was ongoing, more casual nongraded urologic conferences that you would give to medical students and residents about different aspects of urology but I was never on the sort of the teaching faculty in a medical school, which at least that's how I define didactic.
Q And since leaving Emory, have you led any similar type of courses in your current practice?
A There have been some courses taught

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at the meetings, at the annual meetings that are given, whether it would be a round table or whether it would be a course given to general urologists who are attending the meetings, but nothing on any given medical campus in a classroom setting.

Q And are those presentations that you gave at the annual meetings included on your CV here?

A Yes, they are.

Q Okay. Is that --

A I think three of them are under courses.

Q -- And that's the microsurgical course, the evaluation of the infertile male and the testicular sperm retrieval?

A Yes.

Q Okay. Are there any other courses or presentations that you've led since, other than those three, since leaving Emory?

A Yes.

Q Okay. And what are those? What have those been on?

A They were primarily focused on -- I think the topic was microsurgical

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reconstruction and that was given I believe in -- if I can remember right, '90 -- no, that would have been 2000, 2001, 2002 and 2003 if I remember right.

Q At what meeting would those have been given?

A American Urologic Association, the annual AUA meeting.

Q And microsurgical reconstruction, does that refer to a reverse vasectomy?

A Yes.

Q Okay. You have on your CV a study listed called a placebo controlled safety and efficacy study about alprostadil alphadex?

A Yes.

Q In the treatment of erectile dysfunction?

A Right.

Q Now alprostadil is the active ingredient used in Caverject, right?

A Correct.

Q Was it one of those two products that you were investigating at the time?

A Yes.

Q Which one?

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A MUSE.

Q And when was that study conducted?

A That would have been 1994.

Q And you're listed as the principal investigator. Were you the principal investigator at Emory?

A Correct.

Q You weren't the principal investigator for the entire study, were you?

A That's correct.

Q Okay. And do you know how many sites were involved in that study?

A It would be a guess and I would have to say at least ten.

Q And how many patients did you oversee at Emory as part of the MUSE study?

A Boy, that's a great question. Probably around 50 I would think.

Q And were they randomly assigned as to placebo --

A Yes.

Q -- versus active ingredient?

A Correct.

Q And were you involved in the analysis of the data from that study?

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A No, I was not.

Q And did you publish any papers arising out of that study?

A I don't believe so. Not that I recall.

Q Have you conducted any other studies on any erectile dysfunction treatments?

A No.

Q The study that we just talked about regarding MUSE, who sponsored that study?

A What was her name. They were based out of San Francisco. It would have been -- yeah, I'm blanking on the name.

Q Was that Vivus?

A Yeah, Vivus, that's right.

Q Vivus?

A Exactly.

Q And they actually went onto manufacture and market MUSE?

A They did.

Q When Vivus sponsored the study, they paid the expenses involved with the study?

A They did.

Q And did they pay part of your salary involved in that study?

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A They did not.
Q Okay. That went to the university -- their sponsorship went to the university?
A You know, I don't believe there was a financial stipend that went to the university. I think they just purely sponsored the costs of doing the study.
Q And supplied you with the medication?
A Yes, exactly and protocols.
Q And did they provide you with the training necessary to conduct the study?
A They did. I mean, they went over the protocol and we trained somebody on site, you know, to help conduct the study. I think she was a nurse. And they went over how to collect the data and how to present the data, how to, you know, download the data back to them.
Q And what was your specific role during the course of the study?
A It was to evaluate the men at the initial entrance to the study, get -- you know, make sure they signed all the consents, were aware of all the risks and complications, do the initial evaluation, and then just monitor, you know, their responses and any sort of

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adverse events that developed.
Q And the fact that the study was sponsored by Vivus or Vivus, did that influence the way you evaluated any of your patients?
A No, not really.
Q You said not really?
A Yeah. I would say no.
Q Did it influence the way in which you collected information about these patients?
A No.
Q Did it influence the way you reported the information about these patients?
A No.
Q Other than the study -- strike that. You also have listed on your CV a study on the effects of artificially stimulated ejaculation in the acutely injured spinal cord patient?
A Yes.
Q What was the purpose of that study?
A That was to determine if there was an interval of time immediately after injury during which seminal quality was better than what it would be with advancing time and if there was a window where seminal parameters were optimal, then it would be during that time

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that you would want to potentially collect the specimen and use it for long-term storage.
Q Who designed the protocol of that study?
A I did.
Q And this was also while you were at Emory?
A Yes.
Q What was the timeframe of the study?
A It was over the course of I think 1993 to 1995.
Q And was Emory the only center involved with that study?
A Well, yes. Yes. The patients were located at Shepherd Spinal Cord Center so we would see patients there on some occasions but the funding, at least the grant, was all based out of Emory.
Q And that grant was given by the Paralyzed Veterans of America Spinal Cord Research Center?
A Yes.
Q And did you publish any papers out of that study?
A We did. We published an abstract,

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which I believe was -- should be under abstracts. Yeah, that was number 17 under abstracts.
Q The results of rectal probe electroejaculation in the spinal cord injured patient within two months of injury?
A Correct.
Q And was a full paper ever published?
A No.
Q Other than these two studies that you listed on your CV, have you participated in any other research studies?
A No.
Q Have you ever done any other work for any pharmaceutical company?
A No.
Q Now you're not an ophthalmologist, correct?
A Correct.
Q And you don't treat patients with any type of eye disease, correct?
A Correct.
Q And if a patient came in complaining of any sort of visual problem, you would refer them to an ophthalmologist, correct?

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A Yes.
Q Do you treat patients with hypertension?
A No.
Q Do you treat patients with diabetes?
A No.
Q Do you consider yourself an expert in epidemiology?
A No.
(Whereupon, Witt Exhibit No. 2 was marked for identification by the court reporter.)
Q I want to show you what we've marked as Exhibit 2 and I believe you have a copy of this in the papers you brought with you. This is a copy of the subpoena that was issued for your deposition today. You've seen this document before?
A Yes.
Q And this first page, which is the actual subpoena, you brought a copy of that with you today?
A Yes.
Q And I think you mentioned to me before we started that Attachment A to the

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subpoena was missing from your copy?
A Correct.
Q Okay. Have you seen Attachment A before?
A I have.
Q When was the first time you saw a copy of the subpoena that we've marked as Exhibit 2?
A Let's see. I believe it was December 4th, 2008.
Q December 4th?
A No. That would have been -- that was the initial -- no, that was the initial report. That would have been -- it was sometime in January.
Q You'll see that the subpoena is signed December 24th, 2008 on the front page?
A Correct.
Q Do you know about how long after that that it would have been that you first saw the subpoena?
A It would probably have been the week after that after Christmas.
Q Okay. And at the time you received the subpoena, was Attachment A included in what

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you received?
A Yes.
Q And tell me what you did to respond to the request in Attachment A?
A I just made sure -- I tried to get as much of that documentation that I had available.
Q And did you check your e-mails?
A You mean after?
Q After you received this, did you check your e-mails --
A Yes.
Q -- to download any responsive information?
A I don't quite understand the question.
Q Okay. Well, let me point you to number six on the Attachment A, request all correspondence or other documents reflecting communications with anyone regarding your opinion or testimony in this litigation or its subject matter including but not limited to e-mail correspondence. Do you see that?
A I do.
Q And did you see that at the time you

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received the subpoena?
A Yes.
Q Have you had e-mail correspondence with anyone about this case?
A I have. There was -- I had like this e-mail from Jason Richards.
Q And this is an e-mail dated December 1, 2008 from Mr. Richards. It says, attached is a caption for your report for the Martin Stanley cases. I'll be at the office until 5:00 p.m. central time and can be reached on my cell phone and gives his phone number. Did you have any other e-mail correspondence with anyone regarding the litigation?
A There was these documents for the patient records.
Q The CD's that you brought with you?
A Right.
Q And you got those by e-mail or they were mailed to you?
A These were mailed to me and then they had sent some -- what did they send on line. They sent -- there was one other thing sent on line. I can't recall what that was. There was one other thing that was sent on line. I'll

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try to remember what that was.
Q Okay. Let's -- let's start with this. When were you first contacted by anyone on behalf of the plaintiffs in this litigation?
A Early -- no, late November.
Q And who called you? Who contacted you?
A Jason Richards.
Q And how did he contact you the first time?
A By phone.
Q And had you worked with Mr. Richards before?
A I don't recall. I think either I had peripherally or he had worked with somebody who had worked with me.
Q And do you know who that was?
A Yeah, I don't.
Q Okay. And what did Mr. Richards tell you when he first called you in late November of 2008?
A He asked if I would be able to review these cases for him and issue a statement regarding sort of my impression of these cases specifically.

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Q Did he tell you anything else about the status of the litigation?
A He mentioned that there was a deadline for getting the statement generated and I believe that was sometime in the first week of December.
Q Anything else that you recall he told you during that initial conversation?
A No. I just said send me the records; I'll look at them and try to, you know, get something written to you and then you can tell me if that's, you know, if that's what you're looking for and you can let me know if you want to go ahead with it.
Q And did he tell you anything about Mr. Martin or Mr. Stanley during that first conversation?
A No, other than he mentioned it was a case ongoing with Pfizer because of potential complications from the use of Viagra.
Q Okay. After you spoke with him, they sent -- Mr. Richards sent you the CD's with the medical records? Is that the right timeline?
A Yes.
Q About how long after you first spoke

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with him did you receive the medical records?
A Pretty quickly. I would say within four or five days.
Q And you received the two CD's that you have before you?
A (Witness nods head affirmatively.)
Q Yes?
A I did.
Q Do you know which medical records are on those CD's?
A I do.
Q Which records?
A There's extensive sort of medical records of both Richard Stanley and Richard Martin involving sort of their medical care and their ophthalmologic care and then there's a bunch of other files on there, too.
Q Did Mr. Richards identify which records in particular you should look at from those two CD's?
A He did not.
Q Other than the two CD's of medical records, did he send you anything else at that time?
A He -- well, when he asked -- he asked

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-- he sent me this caption. I think that's what I got an e-mail. It was a caption for this statement.
Q And that's the e-mail we just referred to dated December 1st?
A Yeah. It was -- the caption came with this and he wanted me to sign that caption and fax it to him. It had to be signed and sent back to him within a certain period of time along with the statement.
Q Okay. Did he send you anything else?
A No.
Q Did he send you any deposition transcripts?
A No.
Q Have you ever seen any of the deposition transcripts?
A No.
Q Did he send you any expert reports from any other expert in the litigation?
A No.
Q Did he send you any medical literature?
A He did. He sent me two articles which are here. Yeah, the two studies on NAION

and their potential association with -- with phosphodiesterase inhibitors.
Q And that's the article by Dr. McGwynn and the article by Margo and French?
A Yes.
Q Had you seen those articles before you received them from Mr. Richards?
A I had not.
Q Other than those two medical articles, were there any other articles that Mr. Richards sent you?
A No.
Q Were there any other articles that you reviewed in the preparation of your expert report?
A Yes.
Q What other articles did you review?
A Wikipedia on NAION and then I went back to some articles I'd read like in like 2002. And I want to say it was by Pomeranz on some of the initial cases that had been reported, that had occurred or at least had been reported with sildenafil and citrate and NAION and there was a smattering of those cases and then there was some abstracts in the

ophthalmological literature most recently, you know, discussing, you know, NAION and its risk factors and, you know, does Viagra increase the risk or not and I forget exactly -- it was just on Pubmen -- it was a list of abstracts that came out with Pubmen.
Q Did you keep a copy of any of the abstracts or articles or listings of the articles you reviewed?
A I did not. I could -- I could get them probably.
Q Did you rely on any of those articles in the preparation of your expert report?
A No. That happened just in the last two weeks so, no, that was well after the report.
Q So that I understand the timing, in preparation of the report -- strike that. Let me start again. So I understand the timeline that occurred, you received the phone call from Mr. Richards; you received the medical records from Mr. Richards together with the McGwynn and Margo and French study?
A Actually these came later.
Q Okay.

A These actually came after the report.
Q Okay. So at the time you prepared your report in this case, the only thing you had reviewed were the medical records?
A Correct.
Q And there was no medical literature you relied upon in preparing your report; is that correct?
A Not at that time, other than what had been discussed at meetings and had been presented, you know, with various abstracts at different meetings, you know, about the potential association between the two but, yeah, nothing -- what I had already sort of seen in the urologic literature.
(Whereupon, Witt Exhibit No. 3 was marked for identification by the court reporter.)
Q Okay. I'm going to mark as Exhibit 3 a copy of the expert report we received in this case. Have you seen that document before?
A Yes.
Q And is that in fact the expert report you prepared in this case?
A Yes.

Q And I believe attached to that is another version of your CV, correct?
A Yes.
Q Or another copy. And if you look at the first page of Exhibit 3, you'll see there's basically a cover page that says expert report of Michael A. Witt, M.D. and then there's a signature line and a date, correct?
A Correct.
Q And is that the caption that Mr. Richards sent to you?
A Correct.
Q And did you in fact sign that on or about December 1st, 2008?
A Yes.
Q How far before you signed the first page, this caption page, had you prepared the report that's attached to it?
A I think on the same day if I remember.
Q So that was all prepared on or about December 1st?
A Yes.
Q And how long before you prepared the report had you received the medical records

about Mr. Stanley and Mr. Martin?
A I would say about a week before.
Q And how much time did you spend on the case before preparing the report?
A It was around two hours I believe.
Q And were those two hours time that you spent reading the medical records?
A Yes, and preparing the report.
Q Now you told me earlier that at the time you prepared the report, you relied on the medical records and also some things that you had reviewed during the course of time --
A Yes.
Q -- in your experience. Is that a fair summary?
A Yes.
Q What articles did you rely upon in preparing the report that we've marked as Exhibit 3?
A I mean none specifically. It was probably just a culmination of everything that I knew about erectile dysfunction, had continued to learn about erectile dysfunction and had stayed current with regarding the treatment of erectile dysfunction specifically

with the phosphodiesterase inhibitors.
Q And the articles that you received from Mr. Richards, specifically the McGwynn and the Margo and French study, those you received after December 1st, correct?
A Yes.
Q Do you know how long after December 1st?
A It would have been around the first or second week of January.
Q And do you know what the reason for sending you those articles was?
A Well, I think I was aware of the deposition and he had called just to say, you know, are you aware of the deposition coming up and, you know, here's what your statement says, you know, have you read these articles. And I said, no, I haven't. He goes, well, I'll send them to you because they talked a little bit about the risks potentially associated with phosphodiesterase inhibitors and NAION.
Q And having read the Margo and French and McGwynn articles now, does that change any of the opinions that you've expressed in your report?

A No.
Q And having gone back and reviewed the other literature you identified for me, does that change any of the opinions as expressed in your report?
A No.
Q Was there any draft of the report that we've marked as Exhibit 3 that existed before this version that you signed?
A No.
Q You didn't prepare a draft and send it off to Mr. Richards to look at before you signed this?
A No.
Q Between the first conversation you had with Mr. Richards and late November 2008, did you have any other conversations with him prior to December 1st?
A There was a conversation -- actually I think it was on December 1st if I remember right -- about how to get this to him on time.
Q Okay.
A Because there was a deadline and I was supposed to get this out and get this signed and get this to him and I think I sent

it to the wrong office. I sent part of it to the wrong office and so then we had some phone calls that evening about how to get things to him. We kind of figured out how to do it electronically later that evening.
Q And did you have any discussions with him about the substance of what your report said?
A No.
Q Did you have a conversation with anyone other than Mr. Richards about the substance of your report?
A After it had been sent around the time of these, the Margo and McGwynn study were sent, Chris Gomez was in on a conversation we had that was involving these articles and also my report.
Q Okay. So just looking at the different timeframe blocks, between the time you got your first conversation, you received the first phone call from Mr. Richards in November 2008, and the time you signed your report on December 1st, 2008, you had one or two conversations with Mr. Richards, right? The first was about the case and the second was

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about the logistics of getting him the report?
A Correct.
Q Okay. Is that -- is that fair?
A That's fair, yes.
Q And then between December 1st, 2008 and today, before today --
A Yes.
Q -- how many conversations did you have with any attorney representing the plaintiff?
A Two.
Q Okay. And who -- first, when were those conversations?
A I think the first week of January, first or second week of January. That was with Mr. Richards and Mr. Gomez and that was at the time that the Margo and McGwynn studies were sent and they went over again my statement with me. And then I had a conversation last night with Mr. Gomez about, again, the statement and what was said and was I aware of what was in it and have I read it and this is how your deposition will go and do this; don't do this, you know.
Q So going back to the conversation you

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had the first week of January with Mr. Richards and Mr. Gomez, what did they tell you about the Margo and French and McGwynn articles?
A Well, they'd asked me what articles I had read and knew about and then in that -- those lists, this wasn't included and they said have you read these. And I said, no, and they said these tend to imply there may be an associated risk and if you haven't read them, you probably should read them. And I said, fine, you know, send them and I'll read them and then that's -- then they sent them at that point.
Q And what else do you recall about that conversation during the first week of January with Mr. Richards and Gomez?
A I think I queried them just, you know, what was the nature of the case. I didn't really know specifically the details and, you know, what are the issues on either side; who's trying to say what; and so I think we had a brief conversation about why the case existed and where it was going and what the issues were.
Q And what do you recall them telling

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you about that?
A Well, that's when I was really aware that it was about, you know, specifically the use of NAION, an instance of NAION or the potential occurrence of NAION after the use of phosphodiesterase inhibitors, which Pfizer manufactures and there was an intent to sort of figure out, you know, when is there a causation or not and, you know, how do you practice in regards to your awareness of this issue and so we had a conversation sort of around those topics.
Q And then you said last night you had a conversation with Mr. Gomez?
A I did.
Q And how long did that conversation last?
A Maybe 15 minutes.
Q And that was on the phone or in person?
A Phone.
Q And tell me going back real quick to the conversation the first week of January, how long were you on the phone during that conversation?

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A I would say 15 minutes maybe.
Q And tell me what you remember about the conversation last night with Mr. Gomez?
A He just wanted to make sure I had read everything, that there was -- you know, I was aware of what was in my statement here. So we kind of went over that again. He said, are you aware you said this; are you aware he said this. And then just, you know, the nature of a deposition, you know, what not to say, you know, what not to try and do, those kind of things.
Q Was there anything specific Mr. Gomez told you not to say?
A Well, he said don't overreach --
MR. GOMEZ: Objection.
A -- so I said that's fine and I said I'm not an expert in ophthalmology here so I don't want to, you know, how do I talk about this but not be an expert in it because I've fallen into that trap before in depositions.
Q And anything else you remember about that conversation last night?
A That was about it. He just said stick to your statement and, you know, and know

what it's in it.
Q And did you have any discussions with Mr. Gomez today before the deposition started?
A No.
Q Have you submitted any invoices to the plaintiffs for payment yet in this case?
A I have and that was -- it was for two hours and it was after preparation of the statement.
Q And has that been paid?
A That's a review of the medical records and preparation of the statement.
Q Sorry. And has that been paid?
A Yes.
Q And who paid that?
A Oh, boy. I think I sent it to -- I was always confused where to send stuff but I think that went to -- I want to say I think that may have gone to Aylstock, Witkin and Kreis I believe.
Q Had you ever worked with any attorneys from Aylstock Witkin prior to this litigation?
A You know, that's what I can't recall because I was asking how -- why did they get my

name and I never did the diligence to figure out how they got my name but I think I may have but it may have been somebody -- I want to think -- I want to say it was this case that I had back in what was it? Where's my case history here?
Q Let's -- I have a copy of that. I'm going to mark that as an exhibit so we can talk about that --
A There was a priapism case back in November of '07.
Q That was the Kieff versus Chabert case?
A No. Wait a minute.
(Whereupon, Witt Exhibit No. 4 was marked for identification by the court reporter.)
Q While you're looking I'm going to mark as Exhibit 4 a copy of your prior opinion history that we received in this case.
A Yes; correct.
Q Is that in fact --
A It was the Hopkins Roush case. That's -- it was David Doyle so I think that was --

Q March '06?
A I don't remember what firm he was with but I think that may have been the connection but I never figured that out. I was curious though.
Q Now you said that Hopkins versus Roush case involved priapism?
A Yes.
Q And was that a product liability case?
A No. It was a case being brought by an inmate against the health care system of the State of Florida for their detention centers.
Q And you testified on behalf of the defendant in that case?
A Yes.
Q And what was the nature of your opinion?
A The nature of the opinion was that the priapism potentially could have been prevented if it had been addressed and identified, you know, at the proper time but that there were definitely mitigating circumstances that made it very difficult for that to have occurred and there could have been

some better management issues even after identification, you know, of the problem.
Q Are any of these other cases listed on Exhibit 4 product liability cases and do you understand what I mean?
A I do. No, they're not.
Q Are they basically medical malpractice cases?
A Yes.
Q Do any of these cases involve erectile dysfunction?
A Yes.
Q Which cases?
A Massingale versus Lee, Hopkins Roush. I mean indirectly Hulls versus Amin. The primary issue wasn't erectile dysfunction but that was a component of that case, and I think Short versus Raynor I think. I'd have to look back at that. I think Short versus Raynor was.
Q Are those all the ones?
A Yes, that I can remember.
Q Now those four cases, in those cases was erectile dysfunction the injury that was alleged or was that the underlying condition that was being treated?

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A That was the injury that was alleged.
Q In all four of the cases?
A Correct.
Q And so none of these cases involve the treatment of erectile dysfunction as the grounds for the lawsuit --
A Correct.
Q -- correct. Okay.
A Unless -- I mean, technically the Hopkins Roush case is a treatment of erectile dysfunction but not as it's known in the public eye.
Q The treatment of priapism?
A Right, which is erectile -- but, you know, most people think you can't get an erection is erectile dysfunction. But this is getting too much of an erection.
Q Understood. This list that we have as Exhibit 4, is that something you prepared for this litigation or is this a running list that you maintain?
A It's a running list.
Q So when we asked for that, you just printed it up from your computer?
A Yes.

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Q Have there been any additions to this list or changes to this list since you submitted your report on December 1st?
A No, other than this case which isn't on the list yet.
Q Which will be after today?
A Yes. Ys.
Q Has your testimony ever been excluded by a court?
A Not that I'm aware of.
Q Did you have any conversations with Richard Martin prior to writing your report?
A No.
Q Have you spoken with Mr. Martin since you've written your report?
A No.
Q Did you have any conversations with Mr. Stanley prior to writing your report?
A No.
Q Did you have any conversations with Mr. Stanley since writing your report?
A No.
Q Have you ever spoken with any of Mr. Martin's physicians?
A No.

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Q Have you ever spoken with any of Mr. Stanley's physicians?
A No.
Q Have you spoken with either of their spouses?
A No.
Q I take it you've never examined either one of them?
A Correct.
Q And I think you told me you did not review Mr. Martin's deposition transcript, right?
A Correct.
Q And you did not review Mr. Stanley's deposition transcript?
A Correct.
Q Has anyone provided you with a summary of their deposition testimony?
A No.
Q Has anyone provided you with a deposition summary of any of their treating physicians?
A No.
Q Has anyone provided you with the deposition summary of any of Pfizer's

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employees?
A No.
Q Has anyone provided you with a deposition summary of any other expert in this case?
A No.
Q Do you know who any of the other experts in this litigation are?
A No, I don't. I know there's -- Mr. Gomez mentioned there's an ophthalmology expert but he didn't mention the name.
Q Have you done any on-line research about the litigation?
A No.
Q Have you asked anyone to do any such research on your behalf?
A No.
Q I think I asked this question. I just want to make sure I'm clear. Prior to signing your report, did you review the substance of the report with anyone on behalf of the plaintiffs?
A No.
Q Has anyone ever asked you to make any changes to your expert report?

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A No.
MS. LESKIN: I'm told we have to change the videotape so let's take a quick break.
THE VIDEOGRAPHER: 3:00 o'clock we're off the record. This is the end of tape number one.
(Whereupon, the video camera was turned off.)
(Whereupon, a brief recess was taken.)
(Whereupon, the video camera was turned on.)
THE VIDEOGRAPHER: 3:09; we're back on the record. This is the beginning of tape number two.
BY MS. LESKIN:
Q Doctor, I want to talk a little bit about erectile dysfunction generally. You say in your report, you define ED as the inability to obtain and/or maintain male penile erection sufficient for satisfactory sexual performance and that it afflicts over thirty million men in the United States and over a hundred-and-fifty million men worldwide. What is the basis for

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those statistics?
A I believe these are epidemiological studies that have been done by population sampling in general in specific locations such as like the Framingham study that have documented percentages of ED in different age groups and then confirmed by other similar epidemiological studies and other sites internationally and then I think they've extrapolated sort of come up with those numbers.
Q And do you know the years in which those studies were done?
A Not off the top of my head.
Q You mentioned -- you mentioned here that the greatest risk factor for ED is age?
A Yes.
Q And our population is getting older, correct?
A Yes.
Q Would you expect that as the U.S. population gets older, that ED will become a greater problem?
A Yes.
Q You also state here that the primary

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mechanism for ED is vascular dysfunction. What does that -- what's the basis for that statement?
A Well, the corporal tissue is primarily a specialized vascular structure so there are a lot of mechanisms that can affect the integrity of that structure but at the end of the day, it primarily becomes something that's affected the vascular integrity of that structure.
And there are obviously other reasons for erectile dysfunction that aren't vascular in nature but probably the majority of them affect the overall function of that vascular system.
Q And are the majority of erectile dysfunction patients that you see in your practice, patients whose ED is caused by vascular problems?
A If you're asking do they have identifiable vascular etiologies that would be the cause for the erectile dysfunction, probably 50 percent of the time they do and then probably 50 percent of the time they don't. So in some cases, you can't find a

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specific vascular reason though you know there is an -- there's a vascular effect for the symptom but then in the other half, you will -- there will be sort of comorbidities that are known to affect the vascular system in general and corporal tissue directly.
Q So conditions that affect the systemic vasculature will also effect the penile vasculature, correct?
A It can, not always but it can.
Q And so hypertension is a big risk factor for ED, correct?
A Yes.
MR. GOMEZ: Objection.
THE COURT: Overruled.
Q And diabetes is a risk factor for erectile dysfunction?
A Yes.
Q And high cholesterol?
A Yes.
Q And smoking?
A Yes.
Q And those are all conditions that affect the vasculature throughout this body, correct?

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A Yes, it can.
Q Would you agree that erectile dysfunction can be a major health concern for men?
A I would say it's a major concern. It can definitely affect quality of life, which can then indirectly affect health but as a cause of any other significant pathology or disease process, it's a fairly -- it's pretty much an end point, you know, as opposed to the initiating event of some other cascade process that results in deterioration of health.
Q But it could also be a symptom that there are other diseases happening in the body, correct?
A It can be -- I mean, there's some debate as to, you know, if it's a heralding sign of potential risk for vascular integrity throughout the body but, yes, sometimes it can be -- I mean, the penile vascular can come under the same sort of effect that the rest of the body's vascular system can come under from known sort of vascular pathologies such as the one you mentioned.
Q You mentioned the Framingham study

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earlier?
A Yes.
Q That's the Massachusetts male aging study, right?
A Correct.
Q And that's -- the data from that study did in fact suggest that erectile dysfunction is an indicator of arterial insufficiency, right?
A Correct.
Q When a patient comes to you complaining of erectile dysfunction, do you undertake any type of examination to determine the cause of that problem?
A Yes.
Q And what kind of things do you look for?
A Well, we take a pretty thorough history and you want to concentrate on any other medical problem that they have obviously. And you want to get a pretty thorough pharmacological history as well, recreational drug history, and then in examination, you do a blood pressure; you do a pulse; you do a pretty thorough cardiac exam, pretty thorough

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neurologic exam.
If -- if at that point in time, there aren't really any identifiable problems or they don't come in with any known identifiable problems or currently under treatment, then usually you'll check their hormonal profile, get a lipid panel, get a cholesterol panel, maybe a thyroid, a glucose level, and at that point based on sort of how they're responding, determine if there's a vascular study should be done, you know, the penile vasculature with duplex doppler ultrasound.
And then put that together to come up with the diagnosis, identify comorbidities and then come up with a treatment plan or palliative plan potentially for the erectile dysfunction and then a treatment plan for any comorbidities that exist.
Q Have there been patients who have come to you complaining of erectile dysfunction without a known comorbid -- without any known comorbidities in which you have diagnosed such comorbidities?
A Yes. Yes. So there's been patients that have presented with sort of the classic

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metabolic syndrome that -- I mean, we're aware something was going on in terms of the overall weight but maybe had never had it diagnosed, the diagnosis of high blood pressure, have diagnosed, you know, elevated cholesterol levels, have diagnosed new onset of neurologic conditions, whether that be spinal cord mediated or peripherally mediated so, yes.
Q And then so not only can those patients be treated for their erectile dysfunction but they can be treated for other conditions as well?
A Exactly.
Q And you would refer patients then for treatment of their hypertension or their diabetes or other conditions that you've discovered?
A Correct.
Q Now we talked earlier about the study you participated in involving MUSE or what ultimately was marketed as MUSE. Prior to MUSE being available on the market, what did you have available to you as a urologist to treat patients with erectile dysfunction?
A Well, there were the oral agents that

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were out there such as yohimbine, trazodone. There were injectable agents available, oral agents that would be injected into the corporate tissue. There were vacuum devices, penile prosthetic devices, and I'm trying to remember if -- there was some overlap of when the phosphodiesterase inhibitors came out but there was that available, too.

Q But that was much later in time?

A Right.

Q You mentioned a couple of oral therapies yohimbine and trazodone. Erectile dysfunction was not an FDA approved indication for either of those products, correct?

A Correct.

Q And would you use those to treat your patients?

A At that time?

Q Yes.

A Yes.

Q Were they effective?

A No, not significantly.

Q You also mentioned vacuum devices, yes?

A Yes.

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Q And did you prescribe those to your patients to treat their erectile dysfunction?

A Yes.

Q I want to show you -- we can mark it as an exhibit but I'm going to keep custody of these. I want to show you a device which I ask you if you recognize this. I'm going to let you take it apart because I really frankly don't know how to put it together. Is this in fact a vacuum device?

A Yes.

(Whereupon, Witt Exhibit No. 5 was marked for identification by the court reporter.)

Q And we'll mark this Exhibit 5. And can you show us since we do have the benefit of the videotape, how this device worked?

A Well, this device usually consists of a cylinder, which I believe is this structure here, and then it usually consists of a pump that creates negative pressure in the cylinder and you just connect these two up like this.

And then it's optional whether they'll be sort of a constricting ring placed at the base of the cylinder and then this gets

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placed over the phallus and then compressed against the pubic synthesis and then you generate negative pressure with this device, which then will sort of pull blood into the corporal bodies and then you can -- sometimes you apply a constricting device and then release the cylinder and the suction from the skin.

Q I'm going to show you what's been provided to me. Is this the type of constricting device you're referring to?

A This is one but typically they would be more like these. This is what comes with the device and this is one that can be used sort of independent of using any kind of vacuum device is typically how this was marketed but you could use this with a vacuum device.

Q Just for the record, the packaging for the second device is called an actus venous flow controller?

A Yes.

(Whereupon, Witt Exhibit No. 6 was marked for identification by the court reporter.)

Q And we'll term that as Exhibit 6 to

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the deposition.

A Yeah. I think actually MUSE -- I think Vivus actually marketed these.

Q And it's the name that's on the labeling?

A Oh, there we go, yeah. There you go.

Q And how did the venus flow controller work independently?

A You mean how did the actus or how did the vacuum device --

Q The actus.

A I mean, they would use this either independently or so you could use it in sort of mild cases where there was, you know, problems with sort of what's called corporal occlusion versus arterial in-flow and this would work relatively well in those cases and then you could also use it potentially with MUSE as sort of an enhancer, you know, to sort of help trap, especially if there was an occlusive problem.

Q Going back to the vacuum device, was it an effective treatment for erectile dysfunction?

A Well, it would generate a penetratible erection in about 80, 85 percent

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of the cases. It wasn't a normal erection so it wasn't a satisfactory erection for most people but for those who didn't want to do anything more invasive like injections or surgery and whose frequency of intercourse or requirements for erection weren't great, it became, you know, an option.

Q Now. You said it's not a normal erection. What do you mean by that?

A Well, the rigidity you get is only from the pubis synthesis out to the tip of the corporal body. So you have fullness and you have rigidity in that part of the penis but you don't have any sort of corporal expansion of the sort of pelvic-based component of the corpus.

So there's a hinging effect and it creates kind of a floppy erection as opposed to a rigid erection.

Q Were there any complaints from your patients about the vacuum device?

A I mean, it was mechanically a challenge and then it would be the ring would be painful sometimes and it was definitely a learning curve and they didn't like the fact

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that, you know, it wasn't completely rigid all the -- you know, throughout the entire length of the corporal body.

Q And lacks some spontaneity; was that a complaint you heard?

A Not too much because at that point in time, they weren't getting any erection so they were happy just to get what they could get.

Q But patients would use a vacuum device in the absence of an alternative?

A Yes.

Q You also mentioned the prosthetic implant?

A Yes.

(Whereupon, Witt Exhibit No. 7 was marked for identification by the court reporter.)

Q We'll call this Exhibit 7. I believe this is a complete implant. Can you tell us how that worked?

A Well, there's numerous classes of implants. This is an inflatable three-component device and it's composed of two cylinders that sit within the corporal chambers and then there's a pump that sits inside the

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scrotum and then there's a reservoir that sits behind the pelvic bone.

And then this pump will transfer fluid from the reservoir to the cylinders to generate an erection and then there's a release valve that will allow sort of the decompression of the cylinders and the transfer of fluid back to the reservoir for flaccidity.

Q Now this was pretty invasive surgery?

A Yes.

Q The cylinders are actually implanted into the corpus cavity of the penis, correct?

A Yes.

Q Did you perform surgery to implant these devices?

A Yes.

Q What risks were associated with the use of an implants?

A Well, at the -- if you exclude all the procedural risks, it mainly would have to do with infection of the device or malfunction of the device or erosion through the tissue, you know, of the device.

Q Were patients once they had the device implanted satisfied with it?

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A Very.

Q Did you receive any type of complaints about it?

A Well, yeah, the common complaint is that it wasn't as long as they remembered their original erection being. That was a common complaint. Or that they could feel the tubing or that it took longer to recover than what they thought.

But apart from any obvious complaints like it's infected or it's not working anymore, you could remedy most of those complaints by just counseling the patient ahead of time of what to expect and if you could get them to lower their expectations -- the typical response was I wish I'd done that a lot sooner. That was usually the typical response.

Q When you say it wasn't as long as they remember their erection, did you mean by length or by time?

A Length. The advantage of this device is you can generate an erection whenever you want to and you can keep it erect for as long as you want to.

Q It requires manual deflation as

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opposed to ejaculation?
A Yes.
Q And before there was MUSE, there was a product you said an injection called caverject, correct?
A Correct.
(Whereupon, Witt Exhibit No. 8 was marked for identification by the court reporter.)
Q Can you show us how caverject worked? We'll mark that's as Exhibit 8 for the deposition.
A This is essentially an active ingredient. This one is I believe PGE-1, which is a prosthetic gland and it comes in a form and you with this one I believe, you take the solvent and you mix it with the powder. It dissolves and then you draw it back up into the syringe and then you would inject the penis into the lateral side of the corporal body and then inject the required amount to get the erection that you want.
Q And how long before engaging in sexual activity would you have to do the injection?

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A It varies from patient to patient but it's anywhere from five to fifteen minutes.
Q And was caverject effective?
A It was. I mean, caverject is just one of the injectable agents. I mean, if you take all of the type of agents that you can inject, you can generate erections in about 95, 96 percent of the cases.
Q But those all required a syringe that you would inject into the penis?
A Correct.
Q Were patients pleased with caverject?
A Very. But they -- most people, 50 percent of people fall out or at least stop using it because they have to inject themselves, even if it works exactly like they want it to.
Q And what type of side effects or complaints do the patients have from using caverject?
A The biggest one initially and this wasn't with caverject. This was with the initial agents that were used was the erection would last too long. That was the biggest complaint.

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Q Was it painful for men to inject themselves?
A Yes. I mean, it's painful. It's not as painful as they think it is so it's about as painful as giving yourself like an insulin shot.
Q A lot of it is maybe just mental?
A Well, a lot of it is more protective just because most people aren't used to putting a needle into their penis.
Q Did you have complaints from patients that the caverject interfered with spontaneity?
A A little bit. I mean, obviously the problem with it is you always had to have it around and that would create some problems with flexibility but if it was available, it wasn't -- it really wasn't too much of a complaint. It was just I have to inject myself and then you'd get some spousal complaints that they had to use an injection to get the erection.
Q And then we have the MUSE was the next one, correct, and this is the one that you participated in?
A Correct.
Q And I don't have an actual MUSE. I

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just have diagram here.
A Yes.
Q And can you show us how this worked?
A Yes. Well, there was a pellet that was placed in this device that you would insert into the tip of the penis and then you would place the pellet in the urethra itself, which is the urine tube; release it and the pellet would dissolve and it would get absorbed into the corporal chambers here and then it would elicit a vascular response.
Q And how did the entry urethral insertion compare to your patients -- compare to the injection of caverject?
A In regards to what effect?
Q In regards to their willingness to do it. Was it an easier process or a more difficult process?
A I would say most men were more willing to use this as opposed to an injection or at least try it.
Q And what were some of the complaints or side effects that you would receive with MUSE?
A Yeah, the biggest one is that it

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didn't work. And then there was just the burning in the urethra that would be experienced afterwards with the voiding that would occur. Some people would get some blood in the urine but the biggest one was that it didn't work.

Q You said that with the caverject, men dropped out because they didn't want to inject themselves with a needle. Did you have a similar experience with MUSE?

A Not so much because it just wasn't that effective so they dropped out much earlier just because it didn't work. They would move onto another forum.

THE VIDEOGRAPHER: 3:31; we're off the record.

(Whereupon, the video camera was turned off.)

(Whereupon, a brief recess was taken.)

(Whereupon, the video camera was turned on.)

THE VIDEOGRAPHER: 3:32; we're back on the record.

(Whereupon, Witt Exhibit No. 9 was

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marked for identification by the court reporter.)

BY MS. LESKIN:

Q For the record, we're going to mark the MUSE demonstrative as Exhibit 9 to the deposition and, again, for Exhibits 5 through 9 I'll maintain possession of those. I'll represent to you that Viagra was approved by the FDA in March of 1998. Does that sound about right to you?

A Yes.

Q How long after the approval of Viagra -- strike that. When Viagra was approved, did you prescribe it to your patients?

A Yes.

Q And how long after it was first approved, did you start prescribing Viagra to your patients?

A Almost immediately.

Q And you'll agree that Viagra was the first FDA approved oral treatment for the treatment of erectile dysfunction?

A Yes.

Q What were the benefits that you saw at the time in March of '98 to the use of

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Viagra as compared to the treatments that came before?

A The first was that it was a noninvasive, nonmechanical therapy for treating erectile dysfunction of almost all kinds and -- and it was effective if patients were properly counseled and followed.

Q And what percentage of your patients did you find Viagra to be effective?

A Overall it worked effectively to their satisfaction in about 65, 70 percent of cases.

Q Did you find you needed to titrate patients to the correct dose?

A Yes. More cases you had to titrate them to minimize side effects and maintain efficacy and then the other thing was essentially counseling them about its proper use to get the effect they wanted.

Q When the drug was first approved -- when Viagra was first approved in March of 1998, what information did you review prior to prescribing it to your patients?

A Well, you'd go over the side effect profile. You would make sure they weren't on

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any nitrates or Alpha blockers and at that point in time, there was some debate as to, you know, how cautious you should be in administering the patients with a history of cardiac disease, a recent MI or, you know, on more than one anti-hypertensive agent.

Q And what did you personally review -- before you wrote your first prescription, what did you personally review about Viagra to learn about the drug?

A Well, obviously the studies had been presented at the AOA so most of us knew sort of how it worked and I had a pretty close working relationship with one of the guys who did sort of the initial smooth muscle studies on the phosphodiesterase inhibitors so we also had an idea of what it was and how it worked and what some of the side effects were. So I mean, I don't know if there was anything specifically I reviewed on the day it was released other than what had already been presented, you know, at meetings and in the literature.

Q You said you had a good working relationship with the person who did the smooth muscle studies. Who was that?

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A That was Inego Atta (phonetic).
Q And where was he?
A He was at Boston University at that time.
Q Did you speak to anyone at Pfizer before you first started prescribing Viagra to any of your patients?
A No. No, I did not.
Q Did you read the printed package insert for Viagra before you started prescribing it?
A Yes.
Q Now you said when the drug first came out -- I want to focus on that March 1998, early 1998 timeframe -- you used to review the side effect profile with your patients?
A Correct.
Q What information did you include in that profile?
A Well, it was that you had to look for if there was any contraindication for being on the drug. You had to look for headache, dyspepsia, nasal congestion, flushing, visual disturbance, mainly what sort of color, and then lower back pain and erection that lasted

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too long, those kinds of things.
Q You mentioned visual disturbance. What was your understanding of the visual disturbance associated with Viagra at the time the drug was first approved?
A Well, it was known that it had some crossover effect with the phosphodiesterase inhibitor, you know, six and so that obviously had higher concentrations of rods and cones and there would be some changes in either color perception or sense of waviness in the eye that they could experience and they just need to be aware of.
Q And you -- you understand that that visual disturbance is different from the NAION that this litigation involves?
A Yes. Yes.
Q And do you have any opinion as to whether the visual disturbances caused by the effects on PDE-6 is at all related to ischemic optic neuropathy?
A I don't.
Q You don't have an opinion one way or the other?
A Yeah, I don't know. I would just say

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I don't know.
Q Okay. Do you have an understanding as to the half life of the drug?
A Well, the Viagra half life typically would be close to, you know, three to six hours, sort of in that range, you know, based on the dose they used and what else they took or had in their stomach at the time of ingestion.
Q Do you continue to -- do you continue to prescribe Viagra to your patients?
A I do.
Q And is there any group of patients that you do not prescribe Viagra for?
A Well, obviously if they're on nitrates, if they're on any kind of Alpha blockers, and then obviously if they have any history of NAION, you know, or, you know, more visual side effects than just sort of color tinge or things of that nature so.
Q Have you ever given any lectures on Viagra?
A I have given -- I mean, I've given talks to medical students and I have given a couple lectures on the comorbidities of

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erectile dysfunction and I believe -- I think those were sponsored by Pfizer if I remember right but they weren't specifically on Viagra.
Q When were those presentations?
A They would have been I think 1996, '97.
Q Before Viagra was approved?
A Or shortly thereafter. Yeah, shortly thereafter.
Q And which medical students?
A These would be medical students that, you know, you would rotate on the service with you and you would tell them about what was coming out. So mainly it would be urology medical students.
Q Is that while you were at Emory?
A No. This would have been, you know, after Emory, you know, when they would rotate up with us, you know, on -- at RBA and they'd sort of rotate with me for a while and then they're rotate with the RA for a while and you talk with them sort of about ED and those kinds of things.
Q And you said these presentations on erectile dysfunction generally -- they were,

they were not or you don't recall whether they were sponsored by Pfizer?
A I don't recall if they were sponsored by Pfizer. I think they were. I think they were.
Q Would you have any records that would indicate whether or not they were sponsored by Pfizer?
A I could probably -- I could probably find those.
Q We'd asked for any records that indicate that any -- whether there's any presentations sponsored by Pfizer.
A Yeah, I can check that.
Q Did you review any of the clinical studies conducted by Pfizer on Viagra?
A No.
Q Did you -- have you reviewed any of the animal studies conducted by Pfizer on Viagra?
A No.
Q Since Viagra was introduced to the market, you know that there's two other PDE-5 inhibitors that have since been approved by FDA in the United States?

A Yes.
Q And that's Cialis and Levitra?
A Correct.
Q Do you prescribe Cialis or Levitra to your patients?
A I do.
Q And what is the main difference between the drugs as you understand it?
A Mainly has to do with absorption and length of effect, you know, based on their half life.
Q And is there any class of patients that you would prescribe one of the drugs for versus the other?
A No.
Q How do you decide which drug to prescribe to patients?
A Well, a lot of it depends on patient preference. They're so well marketed that patients usually have an idea of what they want to start using, which is fine. If they're not familiar with it or haven't experienced or don't have any experience with the drug, I'll usually recommend starting with one of the shorter acting agents like Levitra or Viagra so

if they get side effects, it has sort of a shorter duration of effect. But, you know, guys who run Viagra will switch to Cialis and guys who run Cialis will go back to Viagra and some will take both. It's just very -- it's kind of, you know, whatever they -- the patient really prefers.
Q Would you say the majority of your patients is on one drug versus another right now?
A I would say it's pretty even. If there's one that has a slight preponderance, it would probably be Cialis but I haven't studied that specifically. But I would it's pretty -- I would say it's pretty even across the board.
Q And when you go through with patients the side effect profiles and the other information you told us you share with your patients, does it depend -- does it matter which of the drugs they're taking? In other words, does your talk with patients differ depending on which drug you're giving them?
A It's very similar, other than just a discussion of the duration of the effect but in terms of their -- the risk profile and the side

effects they could experience, yeah, it's very similar.
Q Have you generally found that Viagra has been an effective treatment for your patients?
A Yes.
Q And have you found that Viagra is generally a safe treatment for your patients?
A Yes.
Q And it's not your opinion that Viagra should never have been approved, is it?
A No.
Q And, in fact, drugs like Viagra today are the first line therapy for erectile dysfunction treatment?
A Correct.
Q Do you find -- strike that. Did you note any increase in the number of patients coming to you to talk about erectile dysfunction once drugs like Viagra came onto the market?
A In my practice, I did not see a huge increase in the number of patients with erectile dysfunction because my population was pretty much enriched with those patients anyway

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but obviously everybody who had erectile dysfunction wanted to try Viagra.
Q Did you find that men were more willing to talk about erectile dysfunction after Viagra came on the market?
A Yeah, that would be hard to determine. Men were more willing to ask for Viagra because they knew something was available obviously due to the marketing that was out there. Whether those men eventually would have come to the office or not, I don't know.
But there's still a huge number of people that don't seek treatment for ED at all and those numbers are fairly recalcitrant and I don't know -- I think the hope was it would bring a lot of people out of the closet but I think it's helped a little bit but not -- not completely.
Q We talked about some of the other treatments for erectile dysfunction. Do you have patients -- well, do you have patients today who continue to use products like MUSE or caverject?
A Not MUSE. Definitely caverject. Not

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the vacuum device. Definitely the prosthesis.
Q I want to talk a little bit about the information you provide to your patients. We talked about the side effect profile and we talked about the nitrate contraindication and the Alpha blocker warnings.
What do you tell your patients about the nitrate contraindications?
A Well, I just say if they are on nitrates on a PRN basis or continually, that they can't use the phosphodiesterase inhibitors.
Q If a patient is using nitrates intermittently, will you prescribe Viagra to them?
A No.
Q Do you give your patients any information about using nitrates after they have taken a PD-5 inhibitor?
A Well, I'll explain to them that if you -- if you have a cardiac history and it looks like there is a risk for MI and they're not on nitrates, that if you were ever admitted to the ER, you know, or if you ever have any kind of surgical therapy or if your primary

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care physician wants to put you on nitrates, you need to let them know you're on Viagra because a lot of men won't list that as a medication in their pharmacology profile. So they have to make sure that that gets -- I'll counsel them that you need to be sure you mention that.
Q Do you counsel your patients about risks cardiovascular risks associated with sexual activity when you prescribe them one of the PD-5 five inhibitors?
A Not really, not if they're not on nitrates.
(Whereupon, Exhibit No. 10 was marked for identification by the court reporter.)
Q I want to show you what we've marked as Exhibit 10. Do you recognize this as the current label for Viagra?
A Yes.
Q When I say label, the professional product insert, correct?
A Correct.
Q The product information. And have you seen this before?

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A Yes.
Q As labels are updated --
A Much smaller print though.
Q -- yes. As labels are updated, how do you keep track of changes to the information provided?
A Well, either it comes out in the literature obviously. You'll see it first at the meetings because that's where emerging things and things that are in development usually get presented before they're even published and then sometimes with the, you know, in-service that drug representatives provide.
Q I want to direct you to page 12 of Exhibit 10. You'll see -- and this is within the section labeled warnings, right, if you go back to the prior page, you'll see at the top of the page language that says, there is no controlled clinical data on the safety or efficacy of Viagra in the following groups. If prescribed, this should be done with caution. Patients who have suffered a myocardial infarction stroke or life-threatening arrhythmia within the last six months, patients

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with resting hypotension or hypertension, patients with cardiac failure or coronary artery disease causing unstable angina; patients with retinitis pigmentosa. Did I read that language correctly?
A You did.
Q Were you aware of this language in the label before today?
A I was.
Q And you know that this language was added in about November of 1998?
A I didn't know the exact date but, right, I knew it had been added.
Q And it had been added early in the life of Viagra?
A Yes.
Q Okay. Do you have any conversations with your patients about this information?
A Well, in going over their history, obviously if they have sort of unstable angina or recent MI, then typically I'll, you know, I'll counsel them not to use Viagra in those settings. But those are pretty dramatic components of their history.
Q If I could direct your attention to

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page 22 of the label, you'll see there's a section entitled postmarketing experience cardiovascular and cerebrovascular? Yes?
A Yes.
Q And it talks about serious cardiovascular, cerebrovascular and vascular events including myocardial infarction and others have been reported postmarketing in temporal association with the use of Viagra. Were you aware of this paragraph's existence prior to today? Take your time.
A No. I had not read this paragraph before.
Q Okay. So you were not aware that this paragraph had been added to the label in November of 1998?
A Correct.
Q Did you have any conversations with any of your patients regarding the reports of heart attack and sudden cardiac death in patients taking Viagra?
A No, I have not.
Q I'd ask you to turn to page 23 of the label and you'll see there's a section there entitled special senses in the middle of the

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page?
A Yes.
Q Right above overdosage?
A Yes.
Q And there's a paragraph that reads, non-arteritic anterior ischemic optic neuropathy, NAION, a cause of decreased vision including permanent loss of vision has been reported rarely postmarketing in temporal association with the use of phosphodiesterase type five, PDE-5, inhibitors including Viagra.
Most, but not all, of these patients had underlying anatomic or vascular risk factors for developing NAION including but not necessarily limited to low cup to disc ratio crowded disc, age over 50, diabetes, hypertension, coronary artery disease, hypolipidemia and smoking.
It is not possible to determine whether these events are related directly to the use of PDE-5 inhibitors to the patients underlying vascular risk factors or anatomical defects to a combination of these factors or to other factors. Did I read that correctly?
A You did.

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Q Were you aware that that paragraph existed prior to today?
A Yes.
Q And that's a true statement, correct?
A Yes.
Q You don't have any information that would contraindicate any of the information in this paragraph, do you?
A No.
Q When did you first become aware of this paragraph being added to the Viagra label?
A Well, I was aware of this issue I think in the -- like 2002 when some of the first case reports came out and there was some debate going on, you know, in the urologic community about its risk and how should that change, how you counsel patients and whether you should use it. So I was aware of that and then I think I became aware in 2006 that it had actually been added as additional language in the labeling.
(Whereupon, Witt Exhibit No. 11 was marked for identification by the court reporter.)
Q I want to show you what we've marked

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as Witt Deposition Exhibit 11. Have you seen this document before?
A I have not.
Q Okay. This is an FDA statement dated July 8th, 2005, right?
A Correct.
Q And this says FDA updates labeling for Viagra, Cialis and Levitra for rare postmarketing reports of eye problems. And it discusses the new labeling information to talk about the reports of NAION, right?
A Correct.
Q Are you aware of any updates of this information since July 2005?
A I'm not.
Q Now you mentioned that you first became aware of the reports of NAION in 2002, correct?
A Correct.
Q And that's when Dr. Pomeranz published a case series?
A Right, correct.
Q Did you change the -- change the information you provided to your patients at that time?

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A I did.
Q In 2002?
A Yes.
Q And what information did you start providing them in 2002?
A Well, there was just that they had the potential risk for serious visual loss and they had to be aware of that risk reporting symptoms of visual loss acutely and if they had, you know, a history of smoking or history of other retinal issues that they needed to use the medication with much more caution and understand that that was a risk going forward.
Q And when in 2002 did you start counseling your patients like that?
A I mean, I think as soon as that became -- I think it was when -- it was around the time it hit the Wall Street Journal I recall, I believe. But patients were pretty aware pretty quickly, you know, of the problem. So it was sort of -- I remember finding out about it sort of simultaneously, you know, from the literature as well as from patients.
Q Now going back to your report, you have the statement here, a rare side effect

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presumably of Viagra is NAION, right, you wrote that in your report?
A I did.
Q Now when you say side effect, what do you mean by that?
A Mean that in a handful of cases there have been men who took Viagra and then developed sudden visual loss. So it would indicate that there's a potential relationship there that they just need to be aware of that hasn't either been confirmed or disproved but just because of the severity of the nature of the problem, they need to recognize it's a risk and be aware of it.
Q And that's -- in the last sentence of that paragraph you said because of the disabling nature of NAION until a causal link between PDEI's and NAION can be proven or invalidated warnings to physician and the patient must included in all labeling, right?
A Correct.
Q And you put that sentence in there because as of today, it still has not been proven or invalidated whether there's a causal link between drugs like Viagra and NAION?

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A Correct. Correct.
Q Do you prepare any written information for your patients who are taking Viagra or one of the other PDE-5 inhibitors?
A I don't. I usually just refer them to the labeling at this point.
Q And do you give them a copy of the label?
A No. I just -- no. I just say when you get your prescription, be sure you read through the label pretty thoroughly.
Q Now are you offering an opinion in this case as to whether Mr. Martin's NAION was caused by Viagra?
A No.
Q Are you offering an opinion in this case as to whether Mr. Stanley's NAION was caused by Viagra?
A No.
Q In the second paragraph of your report you wrote, both men, referring to Richard Martin and Richard Stanley, suffered from erectile dysfunction were treated with the phosphodiesterase inhibitors, sildenafil citrate or Viagra and developed non-arteritic

anterior ischemic optic neuropathy in association with their Viagra use. What did you mean by in association with?

A Meaning that while they were on their Viagra, they developed their -- they NAION.

Q Okay. And you're not offering an opinion as to the temporal relationship between their use of Viagra and the onset of NAION, are you?

A No, other than they were -- they were on the medication at the time of the occurrence so.

Q And when you say on the medication, you mean they had been taking it over a period of time?

A Correct.

Q But you don't have an opinion as to the time between their last ingestion prior to the onset and the onset?

A No.

Q Now the risk factors for NAION and ED overlap, correct?

A They do.

Q In fact, you wrote that in your report, right?

A Correct.

Q And those are the vascular risk factors that we talking about earlier?

A Correct.

Q And then you said, but not all men who have developed NAION after PDEI use possess these risk factors. And that's a true statement, correct?

A Correct. Yeah.

Q And it's also true that men who develop NAION have not taken a PDE-5 inhibitor, correct?

A Correct.

Q And there's men who take the PDE-5 inhibitors who do not develop NAION?

A Correct.

Q And the fact that there were reports of men who have taken Viagra and suffered NAION, that in and of itself is not proof of the causal relationship, right?

A Correct.

Q Do you have any criticism of the label of Viagra for Viagra as it currently reads?

A No.

Q Do you have any criticism of the label for Viagra at any particular point in time?

A No.

MS. LESKIN: We need to change the tape. So we'll take a break.

THE VIDEOGRAPHER: 4:05; we're off the record. This is the end of tape number two.

(Whereupon, the video camera was turned off.)

(Whereupon, a brief recess was taken.)

(Whereupon, the video camera was turned on.)

THE VIDEOGRAPHER: 4:15; we're back on the record. This is the beginning of tape number three.

BY MS. LESKIN:

Q Dr. Witt, other than the opinions that we talked about today as you've expressed in your report and we've otherwise discussed, do you have -- have you been asked to give any other opinions in this litigation?

A No.

MS. LESKIN: I have nothing further.

MR. GOMEZ: I have no questions.

MS. LESKIN: We're done.

THE VIDEOGRAPHER: 4:15; we're off the record. This is the end of tape number three. This concludes the deposition.

(Whereupon, the video camera was turned off.)

THE COURT REPORTER: Did you want to discuss signature?

THE WITNESS: I'm waiving signature.

THE COURT REPORTER: Do you all need copies of the transcript?

MR. GOMEZ: Yes, thank you.

MS. LESKIN: Yes, thanks.

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(Deposition concluded at 4:25 p.m.)

CERTIFICATE

STATE OF GEORGIA:
COUNTY OF COBB:

I hereby certify that the foregoing transcript was taken down as stated in the caption and the questions and answers thereto were reduced to typewriting under my direction, that the foregoing pages 1 through 100 represent a true, complete and correct transcript of the evidence given upon said hearing, and I further certify that I'm not of kin or counsel to the parties in the case; am not in the regular employ of counsel of any of said parties; nor am I in anywise interested in the result of said case.

This 3rd day of February, 2009.

LYNNE C. FULWOOD,
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